K130380

JUN 1 3 2013

Special 510(k) Summary
(as required by 807.92(c))

Regulatory Correspondent:

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Submitter of 510(k):

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Date of Summary: February 8, 2013

Predicate 510(k) Number: K090474

Special 510(k) Number: K130380

Trade / Proprietary Names: OrthoSensor Knee Balancer

Classification Name: Intraoperative Orthopedic Joint Assessment Aid

Product Code: ONN

Device Classification: Class II

Intended Use: For use as a tool for adjustment of the femoral knee implant to reduce instability from flexion gap asymmetry. The Knee Balancer is sterile, for single patient use.

Device Description: OrthoSensor Knee Balancer provides a means to dynamically balance the knee during knee replacement surgery intra-operatively. The system includes an instrumented trial tibial insert comprising an array of load sensors that

measure the forces applied on its surface and angular positional information after insertion into the space between the tibia and the femur.

Description of Changes to the Device: The proposed updated submission is only to remove the "qualitative reference only" designation from the angular positional information as described in the original submission. The angular positional information, which is displayed alongside the load data, is used with the load data to achieve the same intended use. This results in no change to the device itself as it has the same intended use, operating principles, and physical, operational specifications as compared to the predicate device. The proposed updated submission does not alter the fundamental scientific technology of the device.

The intended use of the modified device, as described in the labeling, has not changed as a result of the proposed updated submission.

Predicate Device: OrthoRex Intra-Operative Load Sensor (OrthoSensor Knee Balancer)– 510(k) # K090474

Completion of Design Control Activities: The changes to the OrthoSensor Knee Balancer were evaluated under design controls and met the same criteria as the original device. The Risk Analysis method used to assess the impact of the modification on the device was Failure Mode and Effects Analysis. The results of risk analysis have determined that there are no new risks associated with the modification on the device. The results of risk analysis are identical for the load data as well as the angular positional data. The verification activity required, based on the Risk Analysis, was bench top performance verification testing as well as design validation and usability testing performed in a cadaver lab setting.

Substantial Equivalence: The proposed updated submission has the same intended use as the predicate and same technological characteristics that do not raise different types of questions of safety and effectiveness and the proposed updated submission is therefore substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

June 13, 2013

Orthosensor, Inc.
% Ms. Kimberlee Washburn
Manager, Regulatory Affairs and Quality Assurance
1560 Sawgrass Corporate Parkway, 4th Floor
Sunrise, Florida 33323

Re: K130380
Trade/Device Name: Orthosensor Knee Balancer
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic instrument
Regulatory Class: Class II
Product Code: ONN
Dated: April 22, 2013
Received: May 07, 2013

Dear Ms. Washburn:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,
For

Peter D. Rumm -S

Mark N. Melkerson
Acting Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) #: K130380

Indications for Use Statement

Device Name: OrthoRex Intra-Operative Load Sensor (Trade / Proprietary name = OrthoSensor Knee Balancer)

Indications for Use: For use as a tool for adjustment of the femoral knee implant to reduce instability from flexion gap asymmetry. The Knee Balancer is sterile, for single patient use.

Prescription Use: **Yes** (Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use: **No** (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Joshua C. Nipper -S

For _____

(Division Sign-Off)
Division of Surgical Devices
510(k) Number: K130380